K051623 1.2

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Brandon Hipsher Specialist, Corporate Regulatory Affairs Telephone: (574) 371-8083 Fax: (574) 372-4605
Date:	June 16, 2005
Trade Name:	*Anatomical Shoulder*™ System Keeled Glenoid
Common Name:	Shoulder Prosthesis
Classification Name and Reference:	Shoulder joint metal/polymer semi-constrained cemented prosthesis 21 CFR § 888.3660
Predicate Device:	Anatomica All-Polyethylene Glenoid Component, manufactured by Zimmer GmbH, K990136, cleared March 1, 1999
Device Description:	The keeled glenoid component is part of the *Anatomical Shoulder* System. It provides surgeons with another bone anchorage option while maintaining the system's articular surface geometry.
Intended Use:	This device is intended for cemented use in the treatment of the following: • Advanced wear and tear of the shoulder joint resulting from degenerative, posttraumatic or rheumatoid arthritis. • Omarthrosis. • Rheumatoid arthritis. • Revision of shoulder prosthesis. • Traumatology: the only cone to be used in traumatological indications is the traumatology cone.

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Comparison to Predicate Device:	Except for a minor modification, the Anatomical Shoulder Keeled Glenoid is identical to the predicate device. This modification does not change the intended use or the fundamental scientific technology. The device is manufactured, packaged and sterilized using the same materials and processes.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: Testing completed as part of the design assurance process demonstrated that this device is safe and effective and substantially equivalent to the predicate device. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2005

Mr. Brandon Hipsher
Specialist, Corporate Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K051623
Trade/Device Name: Anatomical Shoulder™ System Keeled Glenoid
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWS
Dated: June 16, 2005
Received: June 20, 2005

Dear Mr. Hipsher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost, Ph.D
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051623 1/1

Indications for Use

510(k) Number (if known):

Device Name:

Anatomical Shoulder™ System Keeled Glenoid

Indications for Use:

This device is intended for cemented use in treatment of the following:

- Advanced wear and tear of the shoulder joint resulting from degenerative, posttraumatic or rheumatoid arthritis.
- Omarthrosis.
- Rheumatoid arthritis.
- Revision of shoulder prosthesis.
- Traumatology: the only cone to be used in traumatological indications is the traumatology cone.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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